

CLAIMS

We claim:

1. A method for treating a condition with a drug indicated for treatment of said condition, the method comprising the step of orally administering a dosage form containing said drug in a pharmaceutically acceptable carrier wherein said dosage form releases said drug from said dosage form at an ascending release rate for an extended time period.

2. The method described in claim 1 wherein said dosage form is an osmotic dosage form comprising:

(a) a longitudinally compressed tablet core containing a plurality of layers wherein drug is contained in at least one layer and at least one other layer comprises a suitable fluid-expandable polymer;

(b) a semipermeable wall surrounding said longitudinally compressed tablet core to thereby form a compartment having an osmotic gradient to drive fluid from an external fluid environment contacting said semipermeable wall into said compartment; and

(c) an orifice formed through said semipermeable wall and into said longitudinally compressed tablet core to permit drug to be released from within said compartment into said external fluid environment.

3. The method described in claim 2 wherein said longitudinally compressed tablet core comprises two layers and said drug is contained within a first layer and said fluid-expandable polymer is contained within a second layer and further wherein said orifice is formed through said semipermeable wall at a location adjacent to said first layer.

1 4. The method described in claim 3 wherein said osmotic dosage
2 form additionally comprises an immediate-release dose of a drug applied as a
3 coating onto the outer surface of said osmotic dosage form.

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5 5. The method described in claim 2 wherein said longitudinally
6 compressed tablet core comprises three layers and a portion of said drug is
7 contained within a first layer and the remaining portion of said drug is
8 contained within a second layer, wherein the concentration of drug contained
9 within said first layer is less than the concentration of drug contained within
10 said second layer, and wherein said fluid-expandable polymer is contained
11 within a third layer and said orifice is formed through said semipermeable wall
12 at a location adjacent to said first layer.

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14 6. The method described in claim 5 wherein said osmotic dosage
15 form additionally comprises an immediate-release dose of a drug applied as a
16 coating onto the outer surface of said osmotic dosage form.

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18 7. A method for treating ADHD, the method comprising the step of
19 orally administering a dosage form containing a CNS-acting drug in a
20 pharmaceutically acceptable carrier wherein said dosage form releases said
21 CNS-acting drug from said dosage form at an ascending release rate for an
22 extended time period.

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24 8. The method described in claim 7 wherein said CNS-acting drug
25 is a CNS-stimulant drug selected from the group consisting of
26 methylphenidate, d-threo-methylphenidate, amphetamine,
27 dextroamphetamine, methamphetamine, phenylisopropylamine and pemoline.

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29 9. The method described in claim 8 wherein said CNS-stimulant
30 drug is methylphenidate.

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2 10. The method described in claim 9 wherein said dosage form is
3 an osmotic dosage form comprising:

4 (a) a longitudinally compressed tablet core containing a
5 plurality of layers wherein methylphenidate is contained in at least one
6 layer and at least one other layer comprises a suitable fluid-
7 expandable polymer;

8 (b) a semipermeable wall surrounding said longitudinally
9 compressed tablet core to thereby form a compartment having an
10 osmotic gradient to drive fluid from an external fluid environment
contacting said semipermeable wall into said compartment; and

11 (c) an orifice formed through said semipermeable wall and
12 into said longitudinally compressed tablet core to permit
13 methylphenidate to be released from within said compartment into said
14 external fluid environment.
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17 11. The method described in claim 10 wherein said longitudinally
18 compressed tablet core comprises two layers and said methylphenidate is
19 contained within a first layer and said fluid-expandable polymer is contained
20 within a second layer and further wherein said orifice is formed through said
21 semipermeable wall at a location adjacent to said first layer.
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23 12. The method described in claim 11 wherein said osmotic dosage
24 form additionally comprises an immediate-release dose of methylphenidate
25 applied as a coating onto the outer surface of said osmotic dosage form.
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27 13. The method described in claim 10 wherein said longitudinally
28 compressed tablet core comprises three layers and a portion of said
29 methylphenidate is contained within a first layer and the remaining portion of
30 said methylphenidate is contained within a second layer, wherein the

1 concentration of methylphenidate contained within said first layer is less than
2 the concentration of methylphenidate contained within said second layer, and
3 wherein said fluid-expandable polymer is contained within a third layer and
4 said orifice is formed through said semipermeable wall at a location adjacent
5 to said first layer.
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7 14. The method described in claim 13 wherein said osmotic dosage
8 form additionally comprises an immediate-release dose of methylphenidate
9 applied as a coating onto the outer surface of said osmotic dosage form.
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11 15. A method for effectively treating ADHD for a prolonged therapy
12 period of at least about 10 hours comprising administering methylphenidate in
13 a dosage form that provides release of methylphenidate at an ascending
14 release rate over an extended time period.
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16 16. A method for providing plasma methylphenidate concentrations
17 that are substantially smoothly ascending over an extended time period
18 comprising administering methylphenidate in a dosage form that provides
19 release of methylphenidate at an ascending release rate over an extended
20 time period.
21

22 17. A dosage form comprising a drug in a pharmaceutically
23 acceptable carrier wherein, following oral administration, said dosage form
24 releases said drug from said dosage form at an ascending release rate for an
25 extended time period.
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27 18. The dosage form described in claim 17 wherein said dosage
28 form is an osmotic dosage form comprising:

29 (a) a longitudinally compressed tablet core containing a
30 plurality of layers wherein said drug is contained in at least one layer

1 and at least one other layer comprises a suitable fluid-expandable
2 polymer;

3 (b) a semipermeable wall surrounding said longitudinally
4 compressed tablet core to thereby form a compartment having an
5 osmotic gradient to drive fluid from an external fluid environment
6 contacting said semipermeable wall into said compartment; and

7 (c) an orifice formed through said semipermeable wall and
8 into said longitudinally compressed tablet core to permit drug to be
9 released from within said compartment into said external fluid
10 environment.

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12 19. The dosage form described in claim 18 wherein said
13 longitudinally compressed tablet core comprises two layers and said drug is
14 contained within a first layer and said fluid-expandable polymer is contained
15 within a second layer and further wherein said orifice is formed through said
16 semipermeable wall at a location adjacent to said first layer.

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18 20. The dosage form described in claim 19 wherein said osmotic
19 dosage form additionally comprises an immediate-release dose of a drug
20 applied as a coating onto the outer surface of said osmotic dosage form.

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22 21. The dosage form described in claim 18 wherein said
23 longitudinally compressed tablet core comprises three layers and a portion of
24 said drug is contained within a first layer and the remaining portion of said
25 drug is contained within a second layer, wherein the concentration of drug
26 contained within said first layer is less than the concentration of drug
27 contained within said second layer, and wherein said fluid-expandable
28 polymer is contained within a third layer and said orifice is formed through
29 said semipermeable wall at a location adjacent to said first layer.
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1 22. The dosage form described in claim 21 wherein said osmotic
2 dosage form additionally comprises an immediate-release dose of a drug
3 applied as a coating onto the outer surface of said osmotic dosage form.
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5 23. A dosage form containing a CNS-acting drug in a
6 pharmaceutically acceptable carrier wherein said dosage form, following oral
7 administration, releases said CNS-acting drug from said dosage form at an
8 ascending release rate for an extended time period.
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10 24. The dosage form described in claim 23 wherein said CNS-acting
11 drug is a CNS-stimulant drug selected from the group consisting of
12 methylphenidate, d-threo-methylphenidate, amphetamine,
13 dextroamphetamine, methamphetamine, phenylisopropylamine and pemoline.
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15 25. The dosage form described in claim 24 wherein said CNS-
16 stimulant drug is methylphenidate.
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18 26. The dosage form described in claim 25 wherein said dosage
19 form is an osmotic dosage form comprising:

20 (a) a longitudinally compressed tablet core containing a
21 plurality of layers wherein methylphenidate is contained in at least one
22 layer and at least one other layer comprises a suitable fluid-
23 expandable polymer;

24 (b) a semipermeable wall surrounding said longitudinally
25 compressed tablet core to thereby form a compartment having an
26 osmotic gradient to drive fluid from an external fluid environment
27 contacting said semipermeable wall into said compartment; and

28 (c) an orifice formed through said semipermeable wall and
29 into said longitudinally compressed tablet core to permit

1 methylphenidate to be released from within said compartment into said
2 external fluid environment.

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4 27. The dosage form described in claim 26 wherein said
5 longitudinally compressed tablet core comprises two layers and said
6 methylphenidate is contained within a first layer and said fluid-expandable
7 polymer is contained within a second layer and further wherein said orifice is
8 formed through said semipermeable wall at a location adjacent to said first
9 layer.

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11 28. The dosage form described in claim 27 wherein said osmotic
12 dosage form additionally comprises an immediate-release dose of
13 methylphenidate applied as a coating onto the outer surface of said osmotic
14 dosage form.

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16 29. The dosage form described in claim 26 wherein said
17 longitudinally compressed tablet core comprises three layers and a portion of
18 said methylphenidate is contained within a first layer and the remaining
19 portion of said methylphenidate is contained within a second layer, wherein
20 the concentration of methylphenidate contained within said first layer is less
21 than the concentration of methylphenidate contained within said second layer,
22 and wherein said fluid-expandable polymer is contained within a third layer
23 and said orifice is formed through said semipermeable wall at a location
24 adjacent to said first layer.

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26 30. The dosage form described in claim 29 wherein said osmotic
27 dosage form additionally comprises an immediate-release dose of
28 methylphenidate applied as a coating onto the outer surface of said osmotic
29 dosage form.

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1 31. The dosage form described in claim 30 wherein said coating
2 comprises an antidegradation agent.

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4 32. The dosage form described in claim 31 wherein said
5 antidegradation agent is phosphoric acid.

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7 33. The dosage form described in claim 29 wherein said
8 semipermeable membrane comprises cellulose acetate and a flux-enhancing
9 agent.

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11 34. The dosage form described in claim 33 wherein said flux-
12 enhancing agent is a copolymer of ethylene and propylene oxide.

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